UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,346	05/15/2001	Natarajan Ranganathan	KBI-0004	9305

26259 7590 05/31/2002

LICATLA & TYRRELL P.C.
66 E. MAIN STREET
MARLTON, NJ 08053

EXAMINER
DAVIS, RUTH A

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 05/31/2002

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/855,346	RANGANATHAN ET AL.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) 11-16 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-10 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1 - 10, drawn to a pharmaceutical composition, classified in class 424, subclass 735, for example.

   II. Claims 11 - 16, drawn to a method for inhibiting toxin build-up, classified in class 424, subclass 780, for example.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method can be practiced with other materially different products such as non-absorbable polyol fatty acid polyester.

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches (as indicated by the different classification). The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group.

Because these inventions are distinct for the reasons given above and the search required for one group is not required for the other groups, restriction for examination purposes as indicated is proper.

3. During a telephone conversation with Jane Licata and Kathleen Tyrrell on November 2, 2001 a provisional election was made with traverse to prosecute the invention of Group I, claims 1 – 10. Affirmation of this election must be made by applicant in replying to this Office action. Claims 11 – 16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 3, 5 and 7 – 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3, 5 and 7 – 8 are drawn to a composition however are rendered vague and indefinite because it is unclear if applicant intends to use a Markush group as the proper language is not used. Applicant may prefer to insert "the group consisting of" after the phrase "selected from" in each of the claims.

In claim 5, line 2, "the inorganic phosphate adsorbent" lacks sufficient antecedent basis.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1 – 3 and 6 – 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Cavadini et al (US 5968569).

Applicant claims a pharmaceutical composition comprising a probiotic, prebiotic and an ammonia-philic urea-degrading microorganism with high alkaline stability and urease activity, that is micro-encapsulated or enteric coated. The composition further comprises a water adsorbent selected from locust bean gum, psyllium fiber, guar gum and zeolite. The probiotic is a Bifidium or Lactobacillus, the prebiotic is a fructan oligosaccharide or and araban

oligosaccharide and the ammonia-philic bacteria is selected from Bacillus pasteurii, Sporosarcina ureae, Bacillus species and Lactobacillus species KB-I. Alternatively, the probiotic and ammonia-philic urea-degrading microorganism is the same species.

Cavadini teaches compositions comprising encapsulated probiotic microorganisms selected from Bifidobacterium, Bacillus and Lactobacillus (col.3 line 3-33), and fiber selected from inulin, fructooligosaccharides (fructan oligosaccharides), guar gum, carob bean gum (locust bean) (water adsorbents) (col.3 line 67 – col.4 line 3).

Although the reference does not specifically teach the probiotic is ammonia-philic and urea-degrading with high alkaline stability and urease activity, such characteristics are inherent to the named probiotic microorganisms of Cavadini. Therefore, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1 – 3 and 6 – 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul (6180099) in view of Ford (5733568).

Applicant claims a pharmaceutical composition comprising a probiotic, prebiotic and an ammonia-philic urea-degrading microorganism with high alkaline stability and urease activity, that is micro-encapsulated or enteric coated. The composition further comprises a water adsorbent selected from locust bean gum, psyllium fiber, guar gum and zeolite. The probiotic is a Bifidium or Lactobacillus, the prebiotic is a fructan oligosaccharide or and araban oligosaccharide and the ammonia-philic bacteria is selected from Bacillus pasteurii, Sporosarcina ureae, Bacillus species and Lactobacillus species KB-I. Alternatively, the probiotic and ammonia-philic urea-degrading microorganism is the same species.

Paul teaches a compositions comprising inulin, guar gum, fructo-oligosacchraides, and a bacteria selected from Lactobacilli and Bifidobacteria (abstract) for gastrointestinal health (col.1 line 27-32). Although the reference does not specifically teach the microorganisms are ammonia-philic and urea-degrading with high alkaline stability and urease activity, such characteristics are intrinsic to the named microorganisms of Paul.

Paul does not teach the composition encapsulated or enteric coated. However, Ford teaches that micro-encapsulating Lactobacilli protects the bacteria from gastric juices and allows them to reach lower intestines where they are therapeutically beneficial (col.2 line 40-56). At the

time of the claimed invention, it would have been obvious to one of ordinary skill in the art wo encapsulate the composition of Paul because it was common to do so as demonstrated by Ford. Moreover, at the time of the invention, one of ordinary skill in the art would have been motivated by Ford and routine practice to encapsulate the composition of Paul, with a reasonable expectation for obtaining an effective composition for gastrointestinal health.

12. Claims 1 – 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul (US 5531988), Ash (US 4581141), Hider et al. (US 5698190), Yatzidis (1979) and Niisato (JP 59110621).

Applicant claims a pharmaceutical composition comprising a probiotic, prebiotic and an ammonia-philic urea-degrading microorganism with high alkaline stability and urease activity, that is micro-encapsulated or enteric coated. The composition further comprises a water adsorbent selected from locust bean gum, psyllium fiber, guar gum and zeolite, and an adsorbent for inorganic phosphate and an adsorbent for uremic solutes other than urea wherein the adsorbent for phosphate is selected from aluminum hydroxide gel, calcium hydroxide gel and magnesium hydroxide gel and the uremic solute adsorbent is activated charcoal. The probiotic is a Bifidium or Lactobacillus, the prebiotic is a fructan oligosaccharide or and araban oligosaccharide, the ammonia-philic bacteria is selected from Bacillus pasteurii, Sporosarcina ureae, Bacillus species and Lactobacillus species KB-I. Alternatively the probiotic and ammonia-philic urea-degrading microorganism is the same species. Applicant additionally claims a pharmaceutical composition comprising a probiotic, prebiotic, an ammonia-philic urea-degrading microorganism with high alkaline stability and urease activity, a water adsorbent, an

adsorbent for inorganic phosphate and an adsorbent for uremic solutes other than urea, that is micro-encapsulated or enteric coated.

Paul teaches a composition for promoting gastrointestinal health comprising an effective amount of Lactobacillus and Bifidobacterium (Bifidum) (abstract). Specifically, Paul teaches Lactobacillus and Bifidobacteria inhibit toxic activities of bacteria in patients with chronic kidney failure (or uremia) (col.2 line 35-40), inhibit overgrowth of gastrointestinal pathogens (col.2 line 60-65) and reduce pathogenic microorganism titers in the gastrointestinal tract (col.3 line 50-55).

Ash teaches compositions containing charcoal and zeolite for removing uremic substances (abstract). Specifically, Ash teaches that charcoal is an adsorbent for uremic substances to include guanidines, creatine, uric acid, drugs, phenols, organic acids and middle molecules (col.2 line 58-63). Ash additionally teaches that charcoal is inefficient in removing water and phosphate, and suggests that a complete sorbent dialyzer must include other sorbents for such substances (col.2 line 65-68). Examples of adsorbents are provided to include zeolite (col.3 line 64-68).

Hider teaches that patients with kidney disorders/diseases who suffer from elevated phosphate levels are traditionally treated with phosphate adsorbents magnesium hydroxide, aluminum hydroxide, calcium hydroxide or mixtures thereof (col.1 line 6-17).

Yatzidis (1979) teaches locust bean gum is an efficient sorbent upon uremic substances to include urea, chloride, uric acid, creatine, ammonia, phosphorus, and sodium (p.105).

Niisato et al. teaches a composition containing fructooligosaccharides for preventing uremia and renal insufficiency (abstract).

The above references do not teach each of the ingredients together in a single composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for treating and/or preventing uremia and kidney disease. Although the references do not teach the compositions are micro-encapsulated or enteric coated, it would have been obvious to one of ordinary skill in the art to do so because it was routine practice in the art at the time of the claimed invention. In support, Ford (US 5733568) teaches that micro-encapsulating Lactobacilli protects the bacteria from gastric juices and allows them to reach lower intestines where they are therapeutically beneficial (col.2 line 40-56). Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to combine the instant ingredients with a reasonable expectation for successfully obtaining a composition for treating and/or preventing kidney disease, failure and uremia.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad
May 28, 2002

LEON B. LANKFORD, JR.
PRIMARY EXAMINER